Asenapine (Saphris) for bipolar I disorder

This Medicine Update is for people with bipolar I disorder who are taking, or thinking about taking, asenapine.

Summary

Asenapine is an antipsychotic medicine. It is used to treat the ‘high’ or manic episodes associated with bipolar I disorder and reduce psychotic symptoms in schizophrenia. This Medicine Update is about using asenapine to treat bipolar I disorder.

Asenapine must be taken correctly to be effective. It comes in the form of a wafer that is placed under the tongue and allowed to dissolve. Asenapine will not work if the wafer is swallowed or chewed, or if you have anything to eat or drink for 10 minutes after taking it. It is taken twice a day.

The wafers look like small round tablets and are fragile so need to be handled carefully. Most people will experience a numbing or tingling effect on the tongue and mouth that may last for up to an hour after taking asenapine.

Most of the other side effects of asenapine are similar to other antipsychotic medicines. Asenapine can cause weight gain, but not as much as some other antipsychotics.

Asenapine is a new medicine and there is limited information about long-term benefits or rare side effects. From the existing evidence, it appears to be about as effective as other antipsychotics, but it is hard to predict how well it will work for a particular person.

www.nps.org.au/medicineupdate
Asenapine (Saphris) for bipolar I disorder

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Asking the right questions about new medicines

What is Medicine Update?

Medicine Update provides independent information about new medicines and new listings on the PBS. It tells you about the possible benefits and harms of new medicines, who can and can’t use them, and some of the other treatment options available.

How to use Medicine Update

Medicine Update is a tool to help you understand your treatment choices and to discuss them with your doctor. Medicine Update doesn’t describe all possible side effects, precautions, or interactions with other medicines — so you should always read the consumer medicine information (CMI) leaflet (see back page).

Who is it for?

Medicine Update is for anyone who is starting this medicine or thinking of starting it, and their carers.

Where does Medicine Update come from?

Medicine Update is written by NPS: Better choices, Better health (NPS) in consultation with consumers and health professionals. NPS is an independent, not-for-profit, government-funded organisation.

NPS takes reasonable care to ensure this information is accurate and up-to-date at the time of creation. It is for your information only and is not medical advice. NPS does not warrant its completeness and excludes liability where permitted by law. We recommend you seek advice from a health professional about your medical condition.
1. **What asenapine is**

The active ingredient of this medicine is asenapine (pronounced a-SEN-a-peen). It is also known by the brand name Saphris. The active ingredient is the chemical in the medicine that makes the medicine work. Many medicines are known by their brand names as well as by the name of the active ingredient. Some medicines are available under several different brand names.

2. **What asenapine is for**

Asenapine is used to treat the ‘high’ or manic episodes associated with bipolar I disorder. It can also be used longer term to prevent these manic episodes from returning. People with bipolar disorder experience extreme moods. For people with bipolar I disorder this includes manic periods of feeling very high and overexcited, as well as ‘low’ periods of depression. During the manic periods, some people experience psychotic symptoms such as delusions, hallucinations and out of control thoughts. During these episodes they may not be able to distinguish what is and isn’t real.

Asenapine is not prescribed to help the symptoms of depression. Bipolar I disorder used to be called manic depression.

3. **Who can take asenapine**

You can be prescribed asenapine through the Pharmaceutical Benefits Scheme (PBS) if you have been diagnosed with bipolar I disorder and are over 18 years of age. Talk with your health professional about all the treatment options for bipolar I disorder.

4. **How to take asenapine**

Asenapine comes in the form of a wafer that looks like a small round tablet. These wafers are very delicate and need to be handled carefully or they will disintegrate.

Asenapine must be placed under the tongue until it dissolves. It is really important that you take it correctly or it will not work. Do not swallow or chew the wafer, and don’t eat or drink anything for 10 minutes after taking it.

There are two different strengths of asenapine — 5 mg or 10 mg. It is usually taken as a single wafer twice a day — one in the morning and one in the evening.
4. **How to take asenapine** …continued

**Steps for taking asenapine**
1. Do not remove the wafer from the blister pack until you’re ready to take it.
2. Make sure your hands are dry before handling the wafer.
3. Peel back the coloured tab on the blister. Do not cut or tear the blister or push the wafer through it.
4. Gently remove the wafer from the blister, being careful not to crush it.
5. Place the wafer under your tongue and allow it to completely dissolve (remember not to chew or swallow the wafer).
6. Do not eat or drink for 10 minutes after taking the wafer.

**Asenapine may make your tongue and mouth feel numb or tingle**
This is quite normal and may last up for to an hour after each dose.

**What if I forget to take asenapine?**
If you forget a dose, take it as soon as you remember and then go back to taking the next dose as you would normally. If it’s already almost time for your next dose, just take a single dose.

Never take a double dose to make up for the one you missed.

**What if I swallow asenapine?**
If you accidentally swallow a wafer, take the next dose when you are meant to. Do not take a second dose.

**How long will I need to take asenapine for?**
Bipolar I disorder usually needs long-term treatment. You will need to take asenapine every day as directed unless your doctor tells you to stop taking it. Even if you’re feeling better, do not stop taking it without talking to your doctor or other health professional.

5. **What does asenapine do?**

Asenapine is a type of medicine called an antipsychotic. It’s one of the newer antipsychotics sometimes referred to as ‘atypical’ antipsychotics.

Antipsychotic medicines work on chemicals in the brain called neurotransmitters. Changes in the levels of these neurotransmitters are related to manic behaviour and psychotic symptoms.

Antipsychotic medicines have a powerful calming effect and help reduce manic behaviour.

**Will asenapine work for me?**
It’s hard to predict which antipsychotic medicine will be best for a particular person.

If asenapine doesn’t work for you, your doctor may change the dose or switch you to a different medicine.

**How long does asenapine take to work?**
You should begin to feel better within a few weeks of starting asenapine.
6. Important side effects to consider

It's very common for your tongue and mouth to tingle or feel numb for up to an hour after each dose of asenapine.

Most people will get side effects from antipsychotics

Asenapine has similar side effects to other antipsychotics. Most of the time these are not serious and they may improve over time.

These are some common side effects of asenapine:
- sleepiness or fatigue (very common)
- dizziness
- drowsiness
- restlessness, agitation, anxiety, excitement or difficulty concentrating
- shaking, twitching or rigid muscles
- increased appetite or weight gain.

Tell your health professional if you feel unwell, even if you are not sure that it’s asenapine that makes you feel this way. They may have some advice to help you manage the side effects, or could decide to adjust your dose or use a different medicine.

Do not stop taking asenapine without talking to your health professional. Your bipolar symptoms can get worse unless you take your medicine as recommended.

Serious side effects you should know about

Asenapine can also cause serious side effects, although these are uncommon or rare. If you have any of the following problems tell your health professional immediately or go to Accident and Emergency at your nearest hospital:
- uncontrollable movements of the tongue, face, mouth or jaw
- extremely high body temperature
- stiff muscles, fast breathing, abnormal sweating or decreased mental alertness
- sudden signs of allergy such as skin rash, itching or hives, swelling of the face, lips, tongue or difficulty breathing.

How to reduce your risk of side effects

Do not take any other medicines that may cause drowsiness (for example, sleeping pills) unless recommended by a health professional who knows that you’re taking asenapine.

Be careful when drinking alcohol, or avoid it altogether, particularly if your health professional has advised you to avoid alcohol. Combining asenapine and alcohol can make you sleepy or dizzy.

To avoid dizziness or fainting caused by a temporary drop in blood pressure, stand up slowly, especially when you get up from a chair or bed.

Dizziness may become less of a problem after you’ve been taking asenapine for a few weeks, but if it continues or gets worse, talk to your health professional.

For a list of all possible side effects, see the consumer medicine information (CMI) leaflet for Saphris (asenapine).

Ask your health professional about the possible side effects of this medicine before you take it.

The terms very common, common, uncommon and rare are used to describe the chance of getting a side effect. This is what they mean:

very common - more than 1 in 10 people (over 10%) might get this side effect
common — up to 1 in 10 people (10%) may get this side effect
uncommon — fewer than 1 in 100 people (1%) might get this side effect
rare — fewer than 1 in 1000 people (0.1%) might get this side effect.

Always tell your health professional about any changes to your condition if you are taking a new medicine.

You can also discuss side effects with a pharmacist by calling the Adverse Medicines Event (AME) Line on 1300 134 237 (Mon–Fri, 9am–5pm).
7. What else you should know about asenapine

Interactions with other medicines
If you’re taking asenapine, you should talk to your health professional before taking any other medicines, including any bought without a prescription from a pharmacy, supermarket or health food store.

Medicines that can interact with asenapine include:

• certain antidepressants, including fluvoxamine (e.g. Luvox) and paroxetine (e.g. Aropax)
• blood pressure lowering medicines.

Tell your doctor about any other medicines you’re already taking before starting asenapine.

Avoid driving or other hazardous activities
Asenapine may make you feel dizzy or drowsy. If it makes you feel this way you should avoid driving, operating machinery or other activities that you need to be alert for.

Asenapine may not be suitable for everyone
Asenapine is not approved for the treatment of people with dementia-related psychosis.

Asenapine may not be suitable if you’re pregnant, about to become pregnant or breastfeeding. Your doctor will take this into consideration before prescribing asenapine.

If you have diabetes or risk factors for diabetes, your blood glucose level should be tested before you start taking asenapine and monitored throughout treatment.

An interaction is when another medicine, food or drink (including alcohol) changes how strongly a medicine works, or changes its side effects in some way.

The interaction may be with a food or food supplement, another prescription or over-the-counter medicine, or a natural or herbal remedy.

The NPS Medicines Name Finder can help you identify your prescription medicines by the active ingredient name and brand name. Find it at www.nps.org.au/medicinenamefinder

Use an NPS Medicines List to help keep track of the medicines you are taking. Take it with you each time you visit your health professional, or if you go into hospital.

Get your free Medicines List or download the iPhone app at www.nps.org.au/medicines_list

8. Other medicines available for bipolar I disorder

You may be prescribed several different types of medicine to treat your bipolar I disorder. Each works differently.

‘Mood stabiliser’ medicines are used to treat and prevent extreme mood swings. They help reduce manic ‘high’ and depressive ‘low’ symptoms.

Lithium is often the first medicine used to treat and prevent manic and depressive episodes. Regular blood tests are needed while taking lithium as it can be toxic if blood levels get too high.

Carbamazepine (e.g. Tegretol) or sodium valproate (e.g. Epilim) are other options. They can be used together or with lithium if needed.

Antipsychotics are used to treat acute manic or mixed episodes. They can be used alone or in combination with a mood stabiliser.

Talk with your doctor or other health professional about all of the treatment options for bipolar I disorder.

Counselling and community support while taking medicines for bipolar disorder is helpful for many people.

Ask your doctor or other health professional to explain why a mood stabiliser, antipsychotic or other medicine is needed for bipolar I disorder, what the benefits are likely to be for you or the person in your care, and how you’ll be able to tell whether it’s working.

A mixed episode is a period where both manic and depressive symptoms are experienced at the same time, or closely together.
8. Other medicines available for bipolar I disorder …continued

Antipsychotics used to treat bipolar disorder

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<td>Saphris</td>
</tr>
<tr>
<td>olanzapine</td>
<td>Zyprexa</td>
</tr>
<tr>
<td>quetiapine</td>
<td>Seroquel</td>
</tr>
<tr>
<td>risperidone</td>
<td>Ozidal, Resdone, Rispa, Risperdal, Rixadone</td>
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<tr>
<td>ziprasidone</td>
<td>Zeldox</td>
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With the exception of ziprasidone (Zeldox), these medicines may also be used longer term to prevent the recurrence of acute manic or mixed episodes.

Quetiapine (Seroquel) can also be used to treat depressive episodes.

Other medicines may be needed for bipolar depression or acute manic episodes

Sometimes you may need an antidepressant to help treat a depressive episode. This will need to be taken in addition to your mood stabiliser or antipsychotic.

During an acute manic episode you may need to take a benzodiazepine (e.g. diazepam) for a short while to help reduce

9. How to decide between asenapine and other medicines

Your doctor will help you weigh up the benefits and side effects of asenapine and other antipsychotic medicines. From the existing evidence, asenapine appears to be about as effective as other antipsychotics, but it’s hard to predict how well it will work for a particular person.

The choice of antipsychotic will be guided by your condition, other medicines you’re taking and your risk of side effects, as well as considerations such as convenience and your personal preference. You may need to try various options before you work out with your doctor what is best for you.

For some people, weight gain may be less of a problem with asenapine compared with other antipsychotics. But it can still occur.

Because the wafer dissolves under your tongue, asenapine may be convenient if you have problems swallowing tablets or liquids. However, some people may find it difficult to use asenapine wafers correctly.

Asenapine is a new medicine. Information on its benefits and possible side effects is still limited, as it has not been studied in a continuous trial for longer than 12 months.

Remember that benefits and side effects differ between medicines and from person to person.

The benefits and side effects of asenapine have been compared with only a few other antipsychotics.

Weight gain can also be caused by your lifestyle and other medicines, including antidepressants and mood stabilisers such as lithium.

You can discuss other options, such as regular injections, with your health professional if you have difficulty taking tablets, liquids or wafers correctly.
10. What does asenapine cost?

Cost to the Government
The full cost of asenapine to the Australian Government is:
- $157.07 for 5mg sublingual wafers (60 in pack)
- $252.72 for 10mg sublingual wafers (60 in pack)

Each prescription is for a 30-day supply of asenapine.

Cost to the individual
If you get asenapine through the Pharmaceutical Benefits Scheme (PBS), the Australian Government pays most of the cost and you will pay only a part, called the co-payment.

At the time of publication, people who are entitled to get asenapine through the PBS will pay:
- $34.20 without a concession card
- $5.60 with a concession card.

If you’re not eligible to get asenapine through the PBS, you will need to pay the full price for a prescription.

Most medicines prescribed by your doctor are covered by the PBS. This means that the Australian Government pays part of the cost of your medicine.

You will need to pay the full price if the medicine is not available on the PBS, or is not available on the PBS for your specific condition.

For more information see www.pbs.gov.au
11. Additional ways to help manage your bipolar disorder

As with other mental health conditions, effective treatment of bipolar disorder should include non-medicine treatments such as counselling and community support programs. Along with medicines, these can play an important role in helping you manage your condition.

Try to live a healthy lifestyle

Studies have shown that regular physical exercise can have a positive effect on mental health. It can also lessen some of the side effects of antipsychotic medicines and this means you’ll be more likely to continue taking your medicines as prescribed.

A common side effect of antipsychotic medicines is weight gain. As well as making you feel less good about yourself, weight gain increases your risk of heart disease and diabetes. So, it’s important to eat well and keep active.

There are various programs designed to help support people with mental illness and improve their physical health. Ask your doctor, or contact SANE Australia to find out about their Mind + Body initiative.

Many people with bipolar disorder smoke. This causes several serious health problems, so quitting is an important step to taking control of your health. The Quitline (137 848) or a health professional can help you increase your chance of success and learn from any past quit attempts.

Look after yourself if you’re a carer

Caring for a person with a mental illness can be stressful and tiring. If you’re a carer it’s vital you look after yourself too, by taking breaks, continuing enjoyable activities, eating a healthy diet, exercising regularly and getting enough sleep. You’ll be able to look after someone more effectively if you’re in good health yourself.

ARAFMI (Association of Relatives And Friends of the Mentally Ill) is an organisation that focuses on providing support for families and others caring for people with mental illness. Each state and territory has a service you can contact for information on counselling, mutual support groups, phone support, information and referral services for families. Contact them through the national Mental Health Carers Arafmi Australia web site at www.arafmiaustralia.asn.au

Psychological treatments may help with depression and anxiety

Psychological treatments, involving talking to a specially-trained health professional, can be an effective method of treating depression and anxiety. Several different types of psychological treatment have been found to be useful for people with bipolar disorder, including cognitive behaviour therapy (CBT) and family support and education. Talk to your GP, psychiatrist or other mental health professional to find out more about whether you might benefit from this type of treatment in addition to taking medicines.

Resources for people with bipolar disorder

beyondblue is a national, independent, not-for-profit organisation working to address issues associated with depression, anxiety and related disorders in Australia.

The Black Dog Institute is an educational, research, clinical and community-oriented facility offering specialist expertise in a range of mood disorders that include depression and bipolar disorder.

SANE Australia is a national organisation working for a better life for people affected by mental illness. They have a range of information and resources available, including:

- Fact Sheet — Bipolar disorder
- Fact Sheet — Antipsychotics
- Mind + Body initiative — promotes physical health and wellness with a range of resources available for individuals and non-government mental health organisations.

Call the SANE Helpline 1800 18 7263 or email helpline@sane.org or visit the website at www.sane.org

NPS acknowledges the contribution of SANE Australia in the production of this article.
Where to find more information

Read the consumer medicine information (CMI) leaflet
The CMI for Saphris (asenapine) will tell you:

• who should not use the medicine
• how to take the medicine
• most of the possible side effects
• the ingredients.

You can get the CMI leaflet for Saphris from:

• your doctor or pharmacist
• the TGA website
• Lundbeck Australia, the suppliers of Saphris (asenapine), on 02 8669 1000.

Information over the phone
NPS works with healthdirect Australia to provide consumers with information on medicines.

To get information about asenapine call Medicines Line on 1300 MEDICINE (1300 633 424) from anywhere in Australia for the cost of a local call (excluding mobiles). Service is available Monday–Friday, 9am–5pm EST except NSW public holidays.

To report a side effect with asenapine
Call the Adverse Medicines Event (AME) Line on 1300 134 237 (Monday–Friday, 9am–5pm EST).

The AME Line lets you report and discuss side effects that might be related to your medicine. Medicine-related side effects are then reported to the Therapeutic Goods Administration (TGA) for assessment and contribute to national medicine safety efforts. Your personal information will remain confidential and your privacy maintained.

For more information about the AME Line visit www.nps.org.au/ame_line

More about using medicines wisely
For more information on how to make wise choices about taking medicines see Medicinewise choices at www.nps.org.au/medicinewise_choices

More information on understanding side effects is available from www.asmi.com.au

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Visit the NPS website to find out about our free activities and resources for consumers
www.nps.org.au/consumers

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